REMARKS

Claims 76-110 are pending. Claim 107 is amended. Applicants are pleased to note that no prior art has been cited, and that Claims 88, 89, 94, 95, and 99 have been indicated to be allowable if rewritten in independent format. As a matter of form, the Examiner's attention is generally drawn to Applicants' U.S. Patent No. 6,322,770, U.S. Patent No. 6,794,518, and U.S. Ser. No. 10/770,380, which are related cases, the latter two being cases where the Examiner is the Examiner of record.

Applicants assume that though the traverse was not deemed persuasive and the requirement proper, the Office Action's statement that "upon further consideration, the restriction requirement of currently presented claims is withdrawn" means with regard to all pending claims.

Claim 107 stands rejected under 35 USC §112, 1st para. and 2nd para., however, Applicants respectfully submit that the enclosed amendment removing the phrase "including stereoisomeric forms thereof, or mixtures of stereoisomeric forms thereof, or pharmaceutically acceptable salt or prodrug forms thereof," from the claim renders the rejections moot. Applicants are not intending to surrender claim scope, considering the phrase is superfluous verbiage and that claim 107 is dependant from broader claims.

Claims 76-87, 90-93, 96-98, and 100-110 are rejected under 35 USC §112, 2nd para., for independent claims 76 and 101 reciting "indazole" and (apparently alternatively) "indazole nonpeptide." Applicants respectfully traverse. When the claims are read in light of the specification as required (e.g., MPEP §2111.01), one skilled in the art would have no difficulty in understanding the ***meaning*** of "indazole."

The term "indazole" is used, for example, in the first paragraph of the detailed

description. *Applicants' specification*, at page 13, line 28. All people skilled in the art, including the Examiner, recognize its meaning, though the term covers numerous compounds. By the Examiner's evidence, over "600 US Patents" recite some type of indazole. In the current compositions, it is intentionally used in its broadest sense, as Applicants are pioneers in this area. **Applicants believe the Examiner takes issue with the term's breadth, but that is irrelevant to definiteness.** See MPEP §2173.04 ("**Breadth Is Not Indefiniteness** [-] Breadth of a claim is not to be equated with indefiniteness. [citation omitted] If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph."). Thus, the rejection is improper. The Examiner's concerns regarding breadth can be addressed by anticipation, obviousness, or enablement. *See* MPEP §2173.04.

Moreover, the Office Action's statement that the "[s]pecification has no definition of an 'indazole nonpeptide'" is somewhat misleading, as the specification defines that "'nonpeptide' means preferably less than three amide bonds in the backbone core of the targeting moiety or preferably less than three amino acids or amino acid mimetics in the targeting moiety." *Applicants' specification*, at page 95, lines 19-22.

Claims 76-87, 90-93, 96-98, and 100-110 are rejected under 35 USC §112, 1st para., as allegedly lacking enablement. Applicants respectfully traverse. The Office Action notes that "extensive experimentation" is required. The Examiner is reminded that "time and difficulty of experiments are not determinative if they are merely routine." MPEP 2164.06. Likewise, "the fact that experimentation may be complex does not necessarily make it undue." MPEP 2164.01. Applicant has provided more than ample direction to those skilled

in the art to make and use the invention.

When rejecting a claim for lack of enablement, the "examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure." MPEP §2164.04 *citing In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). MPEP §2164.04 states:

> The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact.

The Office Action's assertion that "millions and millions" of potential compounds are defined by the claims does not show that the specification fails to teach how to make and/or use the claimed invention, and does not rise to the findings of fact required by the Patent Office. Thus, the Office action has failed to establish a *prima facie* case, as required by MPEP §2164.04. As the enablement rejection is improper, Applicants respectfully request that the rejection be withdrawn.

Moreover, Applicants are not sure that there are "millions and millions" of compounds truly at issue. For example, both independent Claim 76 and independent Claim 101 recite "wherein the targeting moiety binds to a receptor that is upregulated during angiogenesis." In a composition, Applicants' limitation that "wherein the targeting moiety binds to a receptor that is upregulated during angiogenesis" must be treated as a claim limitation. In other words, "an indazole nonpeptide targeting moiety" that failed to bind "to a receptor that is upregulated during angiogenesis," would be outside Applicants' claims. The

Examiner's criticism that "most of these indazoles having interaction with receptors not involved in angiogenesis" proves this point and merely shows examples of indazoles that are not claimed by Applicants, and thus completely irrelevant.

Applicants are equally puzzled by the Office Action's statement that "[n]o compound has ever been found to interact with any or all receptors generally" and "[A]pplicants provided no competent evidence" that the compounds are "useful as antagonists for any or all receptors diseases." Applicants are not claiming a method of treatment. Also, there is no requirement that Applicants engage in clinical testing before filing their application. *In re Brana*, 51 F.3d 1560, 1567-68 (Fed. Cir. 1995) (because pharmaceutical inventions usually require further research and development, incentive to fully research and develop vital drugs and potential cures would be completely removed were such inventions not patentable long before being optimized or ready for human use).

Applicants' disclosure contains sufficient information for one skilled in the art to make and use the claimed invention. The examples and descriptions provide more than an adequate amount of direction for one skilled in the art, which precludes a finding that undue experimentation would be required. Again, the fact that experimentation may be complex does not necessarily make it undue. MPEP §2164.01.

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